

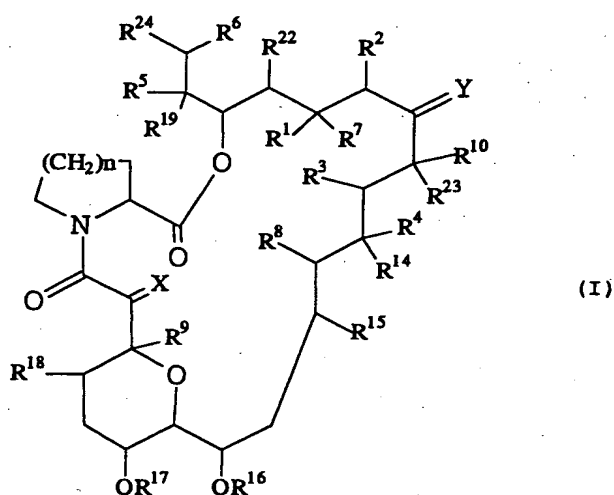
WHAT IS CLAIMED IS

1. A method of treating a human patient suffering from dry eye, wherein prior to treatment said patient has a Schirmer score of less than or equal to seven millimeters per five minutes, said method comprising administering to the patient an ophthalmic composition containing a macrolide compound.
2. A method according to claim 1, wherein prior to treatment said patient has a Schirmer score of less than or equal to five millimeters per five minutes.
3. A method according to claim 2, wherein said ophthalmic composition contains from about 0.01% to about 0.1% of said macrolide compound.
4. A method according to claim 3, wherein said ophthalmic composition contains from about 0.03% to about 0.06% of said macrolide compound.
5. A method according to claim 4, wherein said ophthalmic composition contains about 0.03% of said macrolide compound.
6. A method according to claim 1, wherein said macrolide compound is FK506.
7. A method according to claim 1, wherein said ophthalmic composition is an eye drop.
8. A method according to claim 7, wherein said eye drop further contains polyvinyl alcohol.

9. A method according to claim 7, wherein said eye drop contains about 0.03% of said macrolide compound.

10. A method according to claim 7, wherein said eye drop is administered from about one to about four times per day.

11. A method according to claim 1, wherein said macrolide compound has the following formula (I) or a pharmaceutically acceptable salt thereof:



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wherein adjacent pairs of R^1 and R^2 , R^3 and R^4 , and R^5 and R^6 each independently

a) consist of two adjacent hydrogen atoms, wherein R^2 is optionally alkyl, or

15 b) form another bond optionally between carbon atoms binding with the members of said pairs;

R^7 is hydrogen atom, hydroxy, alkyloxy or protected hydroxy, or may form oxo with R^1 ;

R^8 and R^9 each independently show hydrogen atom or hydroxy;

20 R^{10} is hydrogen atom, alkyl, alkyl substituted by one or more hydroxy, alkenyl, alkenyl substituted by one or more hydroxy or alkyl substituted by oxo;

X is oxo, (hydrogen atom, hydroxy), (hydrogen atom, hydrogen atom), or a group of the formula $-\text{CH}_2\text{O}-$;

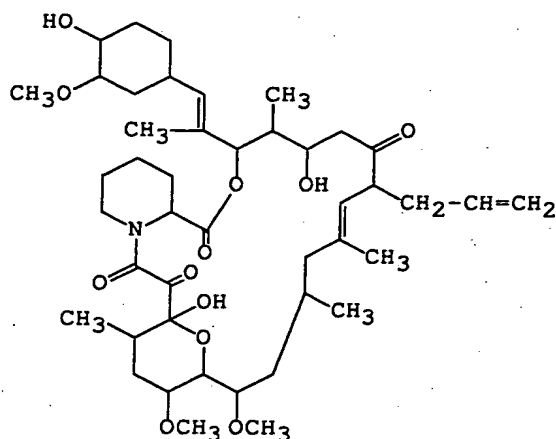
Y is oxo, (hydrogen atom, hydroxy), (hydrogen atom, hydrogen atom), or a group of the formula $\text{N}-\text{NR}^{11}\text{R}^{12}$ or $\text{N}-\text{OR}^{13}$;

5 R^{11} and R^{12} each independently show hydrogen atom, alkyl, aryl or tosyl;

R^{13} , R^{14} , R^{15} , R^{16} , R^{17} , R^{18} , R^{19} , R^{22} and R^{23} each independently show hydrogen atom or alkyl;

R^{24} is an optionally substituted ring that may contain one or
10 more hetero atom(s); and
n is 1 or 2.

12. A method according to claim 11, wherein said macrolide compound has the following structure:



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13. A method according to claim 1 or 2, wherein prior to treatment said patient also has a superficial punctate keratitis (SPK) score of at least two.

20 14. A method according to claim 13, wherein prior to treatment said patient also has a superficial punctate keratitis (SPK) score of at least three.

15. A method of treating a human patient suffering from dry eye, wherein prior to treatment said patient has a superficial punctate keratitis (SPK) score of at least two, said method comprising administering to the patient an ophthalmic composition containing a macrolide compound.
16. A method of treating a human patient suffering from an ocular surface damage associated with dry eye, wherein prior to treatment the patient has a superficial punctate keratitis (SPK) score of at least two, said method comprising administering to the patient an ophthalmic composition containing a macrolide compound.
17. A method of treating a human patient suffering from an ocular discomfort associated with dry eye, wherein prior to treatment the patient has a Schirmer score of less than or equal to seven millimeters per five minutes, said method comprising administering to the patient an ophthalmic composition containing a macrolide compound.
18. A method of treating a human patient suffering from an ocular discomfort associated with dry eye, wherein prior to treatment the patient has a superficial punctate keratitis (SPK) score of at least two, said method comprising administering to the patient an ophthalmic composition containing a macrolide compound.
19. A method of treating a human patient suffering from an ocular surface damage associated with dry eye, wherein prior to treatment the patient has a Schirmer score of less than or equal to seven millimeters per five minutes, said method comprising administering to the patient an ophthalmic composition containing a macrolide compound.